P/2850-101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

Hajime YAMADA et al.

Date: July 30, 2010

Serial No.: 10/516,657

Group Art Unit: 1611

Filed: December 1, 2004

Examiner: Channavajjala, L.S.

For: EXTERNAL MEDICINE FOR TREATING DERMATITIS

Mail Stop AF
Commissioner of Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

The Appellants submit this Pre-Appeal Brief Request for Review pursuant to OG Notice of 12 July 2005. The Notice of Appeal is filed and the fee is paid concurrently with this request.

A separate Notice of Appeal requests the $540 fee be charged to Deposit Account No. 15-0700. A separate request for a two-month extension of time also accompanies this request. If any additional fee is due, the fee should be charged to Deposit Account No. 15-0700.

The Applicants maintain that there are clear errors in the Examiner's final rejections of the pending claims and that the Examiner's rejections omit one or more essential elements required for a prima facie rejection. The bases for these statements are as follows.

1. Summary of Claimed Subject Matter

The pending claims are found in the Amendment of December 10, 2009. The claims recite an external medicine or composition for treating atopic dermatitis and psoriasis vulgaris. The composition includes specific concentrations for (1) adrenocortical steroid, (2) cyclodextrin, (3) dextran or pullulan, and (4) **each of** xyloglucan, trehalose, laminaran, krestin, and pectin. The composition further includes at least one of grape sugar, mutan, lentinan, sodium chloride, or potassium chloride. The claims also recite the method of treating use for the external medicine.

The PCT specification was amended under Article 11 and an "Amended Version.US.Appln" was submitted with the U.S. National Phase for examination. Citations are made to this "Amended Version" of the application.

The Applicants' claimed external medicine is an "aqueous solution." In pharmaceutical terminology, an "aqueous solution" does not contain an "oil." The presence of oil in the vehicle for delivering the medicinals recited by the Applicants' claims is adverse to the treatment of atopic dermatitis and psoriasis as explained by the Applicants' specification. (See "Amended Version U.S. Appln." on page 2 at lines 10 through 13.)

The Applicants' claimed invention provides the unexpected results of delivering effective concentrations of the claimed active ingredients without inhibiting the physiological function of skin. The Applicants demonstrate that the therapeutic value of adrenocortical steroid is enhanced by other specific natural compounds, which are xyloglucan, trehalose, laminaran, krestin, and pectin. This result renders it possible to obtain the synergistic effect of the adrenocortical steroid

and natural healing energy with which the living body itself is equipped. (*See* "Amended Version U.S. Appln." on page 2 at lines 2 through 5, on page 3 at lines 7 through 9, page 7 in Table 1 and at lines 3 through 12, and on page 13 in Table 3 and in the first two full paragraphs.)

2. Grounds of Rejection to Be Reviewed on Pre-Appeal Review

The Examiner's two rejections under 35 U.S.C. § 103(a) rely on the same primary citation of Yamada et al. (EP 0780129), which is the Applicants' previous work. The Examiner acknowledges that "Yamada et al. do not teach xyloglucan (beta-glucan), trehalose, laminaran (beta-glucan), krestin (beta-glucan), and pectin." (*See* the Office Action of September 11, 2009, on page 3 (of the "Detailed Action" section) at lines 2 and 3.) These active compounds are omissions of "essential elements required to establish a prima facie rejection."

The Examiner's two rejections are supported, respectively, by six and seven secondary citations. The secondary citations are a catalog of ingredients, but their individual or combined disclosures contain no teaching, suggestion, or motivation to derive the Applicants' claimed combination of active ingredients in an "aqueous solution."

Only the citations of Yamada et al., JP 240, and Griesbach et al. disclose the treatment of psoriasis vulgaris. The Appellants demonstrated in their response of December 10, 2009, that the treatment of psoriasis vulgaris by the Yamada et al. disclosure is less effective than the results achieved with the Appellants' current claims.

The Applicants explained that Griesbach et al. use various glucans such as *krestin* in Comparative Examples wherein it was determined that the oil-in-water (O/W) skin creams of Examples V1 to V7 have *lower activity* than the activity of Appellants' composition as

demonstrated in Example 1 of the present application. Griesbach et al. use water soluble β-(1,3) glucans, which have intact β-(1,3) side chains and are *free from repetitive β-(1,6) linkages*, as active substances. Griesbach et al. favor a compound that does *not* have β-(1,6) linkages contrary to the Appellants' claims and Griesbach et al. teach away from the claims because the xyloglucan and laminaran *required* by the current claims *have* the β-1,6 linkage.

The Appellants noted in their response of December 10, 2009, that JP 240 discloses a bath powder, which is *entirely unlike* the external medicine for treating dermatitis of the present invention. A bath powder is *not* applied onto skin but into hot water. The skin contacts the hot water wherein trehalose is dissolved in an amount of about 0.00025 % by weight. Example 1 of JP 240 uses 50 g of a bath powder dissolved in 200 L of hot water. This teaching fails to disclose 0.5 to 55% by weight of trehalose as is recited in Appellants' claims and does not teach the absence of oil.

Schmidt uses pectin differently from the use in the Applicants' claims, and Schmidt's allergic contact dermatitis is different from the atopic dermatitis and psoriasis vulgaris. A person of ordinary skill in the art would not combine Schmidt with the other cited references in order to treat atopic dermatitis and psoriasis vulgaris. Schmidt fails to disclose any effect of the compositions described therein upon such atopic dermatitis and psoriasis vulgaris.

Kludas discloses the use of pectin and xyloglucan. However, oils are used in the cosmetic composition and method of treating skin disclosed in Kludas. The Applicants' claimed composition and method does not use oils. Furthermore, the amounts recited in the Appellants' claims (0.5 to 55% by weight) of pectin and xyloglucan also are not disclosed. Still further,

Kludas also fail to disclose any therapeutic effect of the compositions described therein on, specifically, atopic dermatitis or psoriasis vulgaris.

Yvin discloses a dermatological composition including laminarin or laminarin-derived oligosaccharides. However, oils are used in the cosmetics and a skin treatment drug disclosed in Yvin. The Applicants' claims exclude oils. Yvin also fails to disclose any beneficial effect for the compositions disclosed therein upon atopic dermatitis and psoriasis vulgaris.

Mozzone et al. disclose an aqueous topical composition, which contains a water-insoluble anti-inflammatory agent in the form of a gel or a lotion - not a solution. Mozzone et al. fail to make any mention of atopic dermatis and/or psoriasis vulgaris and do not disclose the combination of all of the components required by the Applicants' claims.

3. Conclusion

The rejections are clearly improper and should be reversed. The rejections are improper for relying on citations that omit essential elements required to establish a prima facie rejection.

Favorable consideration of the application is respectfully requested.

Respectfully submitted,

Paul Grandinetti
Registration No. 30,754
OSTROLENK, FABER, GERB & SOFFEN, LLP
1180 Avenue of the Americas
New York, New York 10036-8403
Telephone (212) 382-0700